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EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/10/2004, 10/10/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9,11,15,16 and 18* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *4,7,9,11,15,16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413)

DETAILED ACTION

The examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Examiner Mosher.

Claims 1-3 and 5 remain withdrawn from consideration, being drawn to a nonelected invention. ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/2003 has been entered.

Claims 4, 7, 9, 11, 15, 16, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 includes antigenic fragments of an amino acid sequence which is up to 25% different from SEQ ID NO: 4. Since SEQ ID NO: 4 is 178 amino acids long, 25% of 178 is 44 amino acids. An antigenic peptide can be as small as 6-10 amino acids. Therefore, the "antigenic fragments" of claim 4 include sequences of up to 44 amino acids that have absolutely no relationship to any sequence disclosed in this application. Still further, claim 4 is directed to a protein comprising the antigenic fragments, therefore, claim 4 reads upon

any and all proteins. Since claim 4 encompasses peptides and proteins that are completely undefined, the claim is indefinite. This affects all of the dependent claims.

Claims 4, 7, 9, 11, 15, 16, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 4 is drawn to a Markush group of proteins:

A protein comprising SEQ ID NO: 4

A protein comprising a sequence 75% identical to SEQ ID NO: 4

A protein comprising an antigenic fragment of SEQ ID NO: 4

A protein comprising an antigenic fragment of a sequence 75% identical to SEQ ID NO: 4.

Each member of the Markush group is a genus of proteins. The specification fully discloses one species, the protein consisting of SEQ ID NO: 4. SEQ ID NO: 4 is disclosed as a small part of the polyprotein of a newly-isolated type of virus. The specification provides no guidance as to what portions of SEQ ID NO: 4 are antigenic, and therefore provides no guidance as to what proteins share antigenic portions with SEQ ID NO: 4. Those skilled in the art are unable to a priori predict the structure of epitopes, and are particularly unable to predict the structure of proteins which comprise common epitopes. The specification also provides no guidance as to what 25% of SEQ ID NO: 4 may vary without destroying the basic utility of the protein as a virus antigen.

For these reasons, it is concluded that the specification does not reasonably convey that applicants possessed proteins comprising a sequence 75% identical to SEQ ID NO: 4, proteins comprising an antigenic fragment of SEQ ID NO: 4, or proteins comprising an antigenic fragment of a sequence 75% identical to SEQ ID NO: 4.

This affects all of the dependent claims.

In addition, claim 18 presents an additional "written description" issue, in that it requires a subunit of a virus which has in its genome a sequence at least 75% identical to SEQ ID NO: 1. The specification does not disclose any characteristics of any subunit of a virus. The specification reasonably communicates possession of virions or virus-like particles and three virus isolates, but the specification provides no information on the physical or chemical characteristics of subunits from these viruses. Therefore, it is concluded that the specification does not reasonably convey possession of the subunits required in claim 18.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein comprising SEQ ID NO: 4 or a polypeptide consisting of an antigenic fragment of SEQ ID NO: 4, does not reasonably provide enablement for the full scope of proteins comprising antigenic fragments or variant proteins or fragments of the variant proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification teaches that SEQ ID NO: 4 is part of the polyprotein of a newly discovered type of virus. Although the specification does not provide any evidence that

this sequence can induce an immune response against the virus or any evidence that circulating antibodies of virus-exposed subjects react with this sequence, it is more likely than not that antibodies can be made against SEQ ID NO: 4, and that the antibodies would be able to detect one or more polypeptides made during virus infection. It is also more likely than not that routine techniques such as oliogopeptide mapping would indicate which fragments of SEQ ID NO: 4 have antigenic determinants, without undue experimentation, and that the fragments would be useful in essentially the same manner as the entire SEQ ID NO: 4. Therefore, SEQ ID NO: 4 and its antigenic fragments have an art-recognized utility which can be practiced without undue experimentation. However, the specification provides no guidance regarding what variations may be introduced into the sequence without altering the antigenic nature of the protein, and provides no guidance as to proteins which contain conserved epitopes. Considering the state of the art, the very limited teachings in the specification, and the absence of working examples, it is concluded that undue experimentation would be required to enable the full scope of the invention as claimed.

Claims 7, 9, 11, 15, 16, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 7 is drawn to a diagnostic kit, and claims 9, 11, 15, 16, and 18 are drawn to pharmaceutical compositions and methods. In order to use a diagnostic kit, the specification must enable diagnosis of infection (presumably in a host

organism) using the components of the kit. In order to enable a pharmaceutical composition or method, the specification must enable a body-treating method that achieves a beneficial result, using the components of the composition. The specification teaches that isolated viruses can be used for serological diagnosis, but provides no evidence that sera of virus-exposed subjects react with SEQ ID NO: 4 to any detectable extent. Picornaviruses are known to process their polyprotein into a variety of subunits, and only some of the subunits are routinely used for serological purposes.

Furthermore, the specification provides no evidence that an immune response directed against SEQ ID NO: 4 has any beneficial effect in prevention or treatment of disease. Those skilled in the vaccine and immunotherapy art are unlikely to accept without question unsupported assertions regarding in vivo efficacy, considering the frequent failure of experimental vaccines.

Considering the state of the art, the unpredictability of the art, the limited teachings in the specification, and the absence of working examples, it is concluded that undue experimentation would be required to use the claimed diagnostic and therapeutic compositions and methods.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 7, 11, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hypia et al, PNAS 89:8847-8851, 1992. Applicant's SEQ ID NO:4 contains the sequence VLNRLTYNSSSP at positions 141-152; this 12-mer reasonably constitutes an antigenic fragment of SEQ ID NO:4. The picornavirus polyprotein of Hypia comprises this fragment, see the region at about nucleotides 2210-2250 of Fig.2. Therefore the reference polyprotein meets the limitations of claim 4. Claims 7, 11, and 15 do not require any components other than the protein of claim 4. Therefore the reference polyprotein also meets the limitations of these claims.

The reviews by Rueckert and by Melnick are cited as illustrating the state of the picornavirus art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/26/04

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 /600